One step rapid test for HCV

MERISCREEN HCV

Product code: HCSRPD-01

For in vitro diagnostic use
Read this pack insert thoroughly before use

INTENDED USE:

MERISCREEN HCV is a single test device for the qualitative detection of HCV antibodies (IgM, IgG & IgA) in human Serum/Plasma samples by healthcare professionals.

INTRODUCTION:

Hepatitis C virus(HCV) is now recognised as the primary cause of transfusion associated hepatitis. HCV is a single stranded positive-sense RNA virus and is globally present. In acute presentation of HCV infection patients may develop jaundice, others may go on to develop chronic hepatitis with life threatening conditions such as cirrhosis and hepatocellular carcinoma. Diagnosis of HCV is mainly done by either direct detection of viral RNA by PCR or by detection of anti-HCV antibodies. Recombinant DNA techniques have been used to develop structural and non-structural proteins derived from HCV RNA with utility for antibody screening. Anti-HCV assays have evolved as from 1st generation products, which incorporated NS4 proteins, but the sensitivity was low and then 3rd generation assays evolved which incorporates core (structural), NS3 protease/helicase (non-structural), NS4 (non-structural) and NS5 replicase (non-structural) proteins. Studies report that the third generation assays demonstrate significant improvements in sensitivity, particularly with regard to increased reactivity with the NS3 antigen and earlier detection of seroconversion.

PRINCIPLE:

MERISCREEN HCV a qualitative rapid test based on immuno chromatography principle employs double antigen sandwich site immunoassay on nitrocellulose membrane. As the test sample flows through the membrane assembly of the test device , the recombinant Hepatitis C Virus antigens (Core, NS3, NS4 & NS5)-colloidal gold conjugate forms a complex with HCV specific antibodies in the sample. This complex moves further on the membrane to the test region where it is immobilized by the recombinant HCV antigens (Core, NS3, NS4 & NS5) coated on the membrane leading to the formation of a reddish purple coloured band at the test region 'T' which confirms a positive test result. Absence of this coloured band in test region 'T' indicates a negative test result.
Control band will appear irrespective to the sample status. This control band serves to validate the test results by turning from pale blue to reddish purple color indicating the proper test performance completion. Control band will appear irrespective to the sample status. Control band is the procedural control and it has nothing to do with the intensity of test band(s).

REAGENTS AND MATERIALS PROVIDED:

Each kit contains:

1. Individual pouch each containing Rapid HCV test device with Recombinant HCV Antigens onto nitrocellulose membrane and a desiccant.
2. Assay buffer
3. Disposable Sample Dropper
4. Product Insert
5. Sterile Lancet
6. Alcohol swab

MATERIALS NEEDED BUT NOT PROVIDED:

1. Stop watch
2. Biohazard cover for disposal
3. Hand gloves

STORAGE AND STABILITY:

The sealed pouches in the test kit may be stored between 2-30°C till the duration of the shelf life as indicated on the pouch. DO NOT FREEZE.

PRECAUTIONS:

1. For *in-vitro* diagnostics and professional use only.
2. Allow all reagents and sample(s) to attain room temperature (18°C to 30°C) before use.
3. Test Device is sensitive to humidity; hence use the Test Device immediately once pouch is opened.
4. Do not use the kit contents beyond the expiry date.
5. Do not touch the nitrocellulose part of the device. Finger print or scratch on nitrocellulose membrane may give erroneous results.
6. Test Devices and assay buffers of different lot must not be mixed and used.
7. Perform the test by using kit's assay buffers. Performing the test with any other buffer is not recommended
8. Follow the assay procedure and storage instructions strictly. Deviation will lead to erroneous results.
9. Do not use haemolysed specimen for testing.
10. Use sufficient volume of sample for testing.
11. Do not reuse the Test Devices, sample dropper and pipette tips from the procedure may lead to aberrant results.
12. Do not pipette reagents by mouth and do not smoke, eat or drink while handling specimens and performing a test.
13. Avoid contact of reagents with eyes and skin.
14. Wear protective clothing such as laboratory coats and disposable gloves and eye protection when specimens are assayed. Avoid re-using gloves or use of washed gloves.
15. Handle sample(s) and used materials as if it is capable of transmitting infection.
16. Follow standard Lab procedure and biosafety guidelines for handling and disposal of potentially infective material. Remnants of sample(s), used materials, pipette tips etc. should be disposed in suitable biohazard container. Materials should be autoclaved at 121°C for 15 minutes or dipped in 6 % hypochlorite solution for 30 minutes prior to disposal.
17. Clean up spills thoroughly using an appropriate disinfectant.

SPECIMEN COLLECTION AND PREPARATION:

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

PLASMA:

Collect blood specimen into collection tube containing EDTA, Citrate or Heparin.

1. Separate the plasma by centrifugation, 1500 RPM for 10 minutes.
2. Carefully withdraw the plasma into new pre-labelled tube.

SERUM:

1. Collect blood specimen into a collection tube containing no anticoagulants.
2. Allow the blood to clot.
3. Separate the serum by centrifugation, 1500RPM for 10 minutes.
4. Carefully withdraw the serum into a new pre-labelled tube. Test the specimens as soon as possible after collection.

Stored serum/plasma specimens at 2-8°C up to 3 days can be used for testing. Serum/plasma specimens should be frozen at -20°C for longer storage.

TEST PROCEDURE:

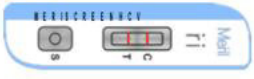
1. Bring all reagents (and specimens) to attain room temperature.
2. Open the pouch and remove the test device from it. Place device on a flat surface.
3. Dispense 10 µL serum or plasma sample through Disposable Sample Dropper on to the sample port ('S').
4. Dispense three drops of the assay buffer into the sample port ('S').
5. At the end of 20 minutes, read the results. Do not read results after 30 minutes.

INTERPRET THE TEST RESULTS AT THE END OF 20 MINUTES. DO NOT READ THE RESULTS AFTER 30 MINUTES AND READING TOO LATE CAN GIVE FALSE RESULTS.

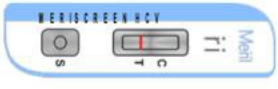
INTERPRETATION OF RESULTS:

NEGATIVE RESULT: If only the Control (C) band is developed, the test indicates that no detectable antibodies to Hepatitis C Virus are present in the specimen. The result is non-reactive for Anti-HCV.

POSITIVE RESULT: If Control(C) and HCV test band are developed, the test indicates for the presence of HCV antibodies in the specimen: the result is reactive for Anti-HCV.



INVALID RESULT: If no Control(C) band is developed, the assay is invalid regardless of colour development on 'Test' band as indicated below. Repeat the assay with a new device.



PERFORMANCE CHARACTERSTICS:

In-house study with a panel of 140 positive and 450 negative samples whose results were earlier confirmed with commercially approved Elisa & Rapid Test kits was tested with MERISCREEN HCV. The results obtained are as follows.

Sensitivity of MERISCREEN HCV: 100 %

Specificity of MERISCREEN HCV: 99 %

LIMITATIONS OF THE TEST:

1. As with all diagnostic tests, the test result must always be co-related with clinical findings.
2. Presence of heterophile antibodies in patient's sample with Rheumatic diseases, Renal failure, Kidney dysfunction and autoimmune disorder may lead to false results need to be reconfirmed with confirmatory tests.
3. A negative result can occur if the quantity of the analyte of interest present in the specimen is below the detection limits of the assay or the analyte of interest that are detected are not present during the stage of disease in which a sample is collected.
4. A negative result at any time does not preclude the possibility of exposure or infection.
5. Repeat the test in case of very faint band or if have any doubt for test band.
6. False negative results may arise because of hook effect due to very high concentration of analyte of interest in sample. Repeat the test by using different dilutions of same sample.
7. This kit is designed for primary screening of HCV infection.
8. Although the test is accurate in detecting Antibodies specific to HCV in Serum/Plasma low incidence of false results may occur. Other clinically available tests such as RIBA, should be used if questionable results are obtained.
9. Interpret the results of the test in immunocompromised patients with caution.

REFERENCES:

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